The Canadian Longitudinal Study on Aging (CLSA)*

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RÉSUMÉ

Les Canadiens vivent plus longtemps et les personnes plus âgées composent une part croissante de la population (14% en 2006, projeté d'atteindre 20% d'ici 2021). L'Étude longitudinale canadienne sur le vieillissement (ÉLCV) est une étude longitudinale nationale portant sur le développement adulte et le vieillissement qui recrutera 50 000 Canadien(ne)s âgé(e)s de 45 à 85 ans et qui les suivra pendant au moins 20 ans. Tous les participants fourniront un ensemble d'informations communes sur plusieurs aspects de la santé et du vieillissement, et 30 000 passeront un examen approfondi couplé au don de spécimens biologiques (sang et urine). L'ÉLCV deviendra une source de données riches pour l'étude d'inter-relations complexes entre les facteurs biologiques, physiques, psychosociaux et sociaux qui affectent le vieillissement en santé.

ABSTRACT

Canadians are living longer, and older persons are making up a larger share of the population (14% in 2006, projected to rise to 20% by 2021). The Canadian Longitudinal Study on Aging (CLSA) is a national longitudinal study of adult development and aging that will recruit 50,000 Canadians aged 45 to 85 years of age and follow them for at least 20 years. All participants will provide a common set of information concerning many aspects of health and aging, and 30,000 will undergo an additional in-depth examination coupled with the donation of biological specimens (blood and urine). The CLSA will become a rich data source for the study of the complex interrelationship among the biological, physical, psychosocial, and societal factors that affect healthy aging.

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* Funding for the Canadian Longitudinal Study on Aging was provided by the Canadian Institutes of Health Research (CIHR), Le Fonds de la recherche en santé du Québec (FRSQ) – Réseau québécois de recherche sur le vieillissement.
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Manuscript received: / manuscrit reçu : 06/08/08

Manuscript accepted: / manuscrit accepté : 02/04/09

Mots clés : vieillissement, développement adulte, études longitudinales, études éventuelles, études complémentaires, études de cohorte, Canada, santé de population, dessin de recherche

Keywords: aging, adult, longitudinal studies, prospective studies, follow-up studies, cohort studies, Canada, population health, research design

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Introduction

Recent advances in biosciences and population health herald exciting opportunities to conduct high-impact population health research. The Canadian Longitudinal Study on Aging (CLSA) is being launched as a program of research and a platform to investigate the complexities of the aging process and improve our understanding of the transitions and trajectories of healthy aging. Despite long-standing awareness that the aging process is accompanied by multifaceted changes during an individual's lifetime, a clear picture of the combined effects of these changes has not yet emerged. The effects of complex interactions among changing biological, psychological, and social factors can take years to unfold, and it is anticipated that these changing factors will manifest themselves differently among tomorrow's seniors (i.e., the baby boomers) than among today's seniors.

If future interventions and policies are to achieve the multiple objectives of improving health, allowing individuals to age optimally into late life, and increasing both quality and length of life, then acceleration of our understanding of the aging process, its modifiers, and consequences is needed. The CLSA will foster cutting-edge research into understanding how biological, physical, psychological, social, and environmental factors individually, and in combination, influence the health and well-being of aging individuals. The CLSA program of research is based on a conceptual framework that will let us examine the relationships among three components: (a) precursors (e.g., gene variants or nutrition); (b) changes in quantitative traits (e.g., cognition or inflammatory biomarkers); and (c) the consequences of the changing phenotype on the development or prevention of disease (e.g., dementia or depression), disability (e.g., frailty or physical limitations), and psychosocial outcomes (e.g., emotional distress or social isolation). Data on social factors including work transitions and retirement planning, health care, and economic factors will also provide evidence to inform social and health care policy. The depth and breadth of data collected will allow this program of research to address questions such as:

- What are the determinants of changes in biological, physical, psychological, and social function over time and across ages?
- How important are genetic and epigenetic factors in the aging process?
- Why do some individuals experience healthy aging while others do not?
- Are there identifiable patterns of cognitive functioning in mid-life that predict onset of dementia in later life?
- How do work and family transitions intersect with negative/positive changes in social networks and support, and how do these transitions influence overall health?

The purpose of this article is to describe the design of the CLSA. The CLSA protocol development has been a collaborative process reflecting the work of the principal investigators together with a multidisciplinary research team comprising more than 160 researchers from 26 universities across Canada. The study design is informed by the results of several feasibility studies that are included in this special issue with detailed reports available on the CLSA website (1).

Methods

Study Design

The CLSA will consist of a national stratified random sample of 50,000 Canadian women and men aged 45 to 85 years[1] at the time of recruitment (baseline). Participants will undergo repeated waves of data collection every 3 years and will be followed for at least 20 years, or until death. The choice of 3 years balances the need to have a short enough interval to capture important changes and map trajectories and the practical consideration of the time required for a complete wave of data collection. Scheduled follow-up visits will be supplemented with a brief interassessment telephone interview to maintain contact and minimize loss to follow-up.

The inclusion of study participants as young as 45 years of age at baseline is motivated by the desire to capture mid-life experiences prospectively, since

https://doi.org/10.1017/S0714980809990055 Published online by Cambridge University Press

important changes known to influence outcomes later in life occur during this period. For example, mobility limitations in mid-life are associated with an increased risk of falls and frailty in later life in the physical health domain and with social isolation and depression in the psychosocial health domain. The lower age limit will also permit inclusion of individuals who are part of the baby boom cohort (i.e., those born between 1946 and 1964), who will be 45 to 63 years of age in 2009. The upper limit includes individuals entering their senior years who are making the transition into retirement, those who are already retired, and those who have already reached old age. One of the interests in studying the oldest age group prospectively is to examine transitions into the final years of life.

All participants will be asked to provide a common set of information on demographic, social, physical/clinical, psychological, economic, and health service utilization aspects relevant to health and aging. This information will be collected via computer-assisted telephone interview. Of the 50,000 participants, 30,000 will also be asked to provide additional in-depth information through physical examinations and biological specimen collection (blood and urine). To participate in the in-depth cohort, participants must agree to the physical examination component but will have the option of refusing to provide biological specimens. The remaining 20,000 (the telephone interview cohort) will be a representative sample of the Canadian population designed to permit provincial-level estimates of health determinants, health status, and health system utilization.

Sampling and Sample Size

Five possibilities for the choice of sampling frame for the CLSA were considered: (a) administrative records such as provincial health insurance plans, (b) telephone directory listings, (c) random digit dialing, (d) the census, and (e) the Labour Force Survey (LFS). With the exception of the provincial health care registration data, census, and LFS, none of the sampling frames if used could guarantee that: first, each individual in the target population is in the sampling frame, and second, each individual has a non-zero probability of being selected.

With the goal of identifying a sampling frame, the CLSA team collaborated with Statistics Canada to assess the feasibility of using one of their surveys, the Canadian Community Health Survey (CCHS), which uses the census as an area sampling frame, as a recruitment vehicle for the CLSA (2). At the same time, the possibility of using provincial health care registration databases as a sampling frame was also investigated (3).

The CCHS is a survey conducted by Statistics Canada every 2 years to produce cross-sectional estimates of health determinants, health status, and health system utilization for health regions and provinces in Canada. In the first year of each cycle ($x.1$), the goal is to provide estimates at the level of 136 regions, and the sample size is large (n ~130,000). In the second year of the cycle ($x.2$), the data are collected to provide estimates at the provincial level, with a correspondingly reduced sample size (n ~30,000). The CCHS is currently in its fourth cycle (i.e., 4.1 and 4.2). CCHS 4.2 is designed to measure healthy aging and thus has provided a unique opportunity for collaboration. Using the CCHS 4.2 as a recruitment vehicle for the CLSA has the advantage that extensive baseline demographic data in the aggregate is available to compare those participating in the CLSA and those who chose not to participate, allowing us to identify selection bias. Although the CCHS 4.2 as a recruitment vehicle is ideal in many respects, the sample size (n = 30,000) will not provide enough participants for both the CLSA telephone interview cohort and in-depth cohort.

The other option that would provide a complete sampling frame for the CLSA is provincial health registration databases. Each province, however, has a unique set of data liberation requirements, which makes obtaining contact information for potential participants difficult. Recognizing this challenge, the CLSA investigators have done extensive pilot work to learn about the province-specific regulations and engage the provincial data stewards and privacy commissioners to help facilitate the use of provincial registration databases as a sampling frame (3).

After careful consideration, it was decided that the CCHS 4.2 would be used as the recruitment vehicle for the telephone interview cohort and that provincial health registration databases will likely be the source for recruitment of the in-depth cohort. Should the CCHS 4.2 not provide enough participants for the telephone interview cohort, then provincial health registration databases will also likely be used to supplement the CLSA telephone interview cohort sample.

The CLSA population will be restricted to those between the ages of 45 to 85 years at baseline who are able to read and speak either French or English. Individuals living in long-term care institutions (i.e., those providing 24-hour nursing care) will be excluded at baseline. However, those living in households and transitional housing arrangements (e.g., seniors' residences, in which only minimal care is provided) will be included. CLSA cohort participants who become institutionalized during the course of the study will continue to be followed either through personal or proxy interview. The final exclusion criterion is the presence of cognitive impairment at the time of recruitment, which precludes the ability to provide informed consent. Interviewers will be trained to identify cognitively

https://doi.org/10.1017/S0714980809990055 Published online by Cambridge University Press

impaired persons and exclude them from taking part in the interview.

Although the 50,000 CLSA participants will be recruited from national sampling frames, and therefore distributed across Canada, the practical requirements of performing physical examinations and collecting biological specimens for the 30,000 participants recruited for the in-depth assessment will stipulate that they be selected proximal to CLSA data collection sites (DCSs). Therefore, individuals residing within a 25-kilometer radius[2] of the 10 DCSs (Vancouver, Victoria, Calgary, Winnipeg, Hamilton, Ottawa, Montréal, Sherbrooke, Halifax, and St. John's) will be over-sampled for inclusion in the group that will undergo a physical examination and have biological samples collected.

Calculation of the required sample size for the CLSA necessitates information on the effect sizes that are desired to be detected. Given the diverse goals of the CLSA and the statistical models required to estimate these effect sizes, it is virtually impossible to take into account global, meaningful effect sizes for sample size calculations. In addition, the use of the CLSA as a platform for future (as yet unknown) research questions precludes such calculations. Consequently, the strategy used to address sample size was to carry out simulations based on the hypothesized evolution of the cohort experience over time. The prevalence of selected exposures along with expected numbers of selected outcomes such as chronic diseases, disability, and functional change over the follow-up period were used as a guide to assess the adequacy of the proposed sample size.

First, the expected number of cases of an outcome was simulated for each 3-year wave of the CLSA based on sex- and age-specific incidence rates and taking into account the aging of the cohort over time. To provide more realistic estimates, the simulations took into account attrition due to loss to follow-up (estimated at 0.5% per year based on information provided by Statistics Canada on the attrition rates for the National Population Health Survey [NPHS] for the period 1994–1995 to 2000–2001) and mortality (based on age- and sex-specific annual mortality rates from Statistics Canada) (4). For example, for a condition with a high incidence rate, such as hypertension (sex- and age-specific incidence rates ranging from 31 to 43 cases per 1,000 persons per year) (5), we would expect almost 3,800 cases by the end of wave 1. In contrast, for a rarer outcome like Parkinson's disease (sex- and age-specific incidence rates ranging from 0.11 to 2.13 cases per 1,000 persons per year) (6), we would expect only 65 cases by the end of wave 1.

A second set of simulations were obtained to estimate the minimum detectable odds ratio (MDOR) between an outcome and exposure. These simulations used the anticipated number of cases of an outcome (from the first simulation) and assumed a range of risk factor prevalence (5%, 10%, 20%, and 50%) representing a plausible range of exposure prevalence. The simulations also took into account potential misclassification of both the risk factor and outcome. We assumed 5 per cent misclassification for the risk factor. For the outcome, we assumed 1 per cent misclassification for those with disease and 10 per cent misclassification for those without disease (i.e., sensitivity = 99% and specificity = 90%).

While the CLSA will not be powered to assess relatively rare outcomes, more common conditions and events will be feasible to detect. Based on 90 per cent power and a two-sided alpha of 0.05, the MDORs for a high incidence outcome such as hypertension range from 2.1 for a rare exposure (5%) to 1.3 for a common exposure (50%). For a rare outcome such as Parkinson's disease, we would have to wait until the end of wave 6 to detect an odds ratio of 1.9 for a common exposure. The use of continuous outcome measures (e.g., cognition) will result in greater statistical power to detect clinically meaningful effects.

Recruitment and Retention

Prior to the launch of the CLSA, several strategies to encourage participation will be put in place. A national public awareness campaign will be launched, including articles in local and national newspapers, broadcast media, public service announcements, brochures placed in the community (e.g., pharmacies), presentations to community organizations, and information for posting in physicians' offices. Both the published literature and the CLSA investigators' previous experience in the conduct of large-scale studies suggest that multiple overlapping strategies are necessary to meet recruitment goals. Continual monitoring and adaptation of strategies will be imperative to ensure that these goals are met.

For the telephone interview cohort, Statistics Canada staff will be responsible for the initial participant contact, the conduct of the CCHS, and the identification of persons who agree to share their contact information with the CLSA. Statistics Canada will approach participants in the CCHS and will forward the names and addresses of persons who agree to the release of their contact information to the CLSA principal investigators. Once this is done, recruitment and all further contact and follow-up will be the responsibility of the CLSA research team. Candidates for the in-depth cohort identified through provincial registration databases will be contacted directly by the CLSA. All potential participants will be sent an introductory letter

informing them that they will be contacted via telephone by a CLSA representative. The letter will contain a CLSA information pamphlet. During the telephone recruitment interview, the interviewer will review the study's purpose.

Based on our pilot work, we anticipate that 55 per cent of the CCHS participants will be willing to share their contact information with the CLSA and that about 60 per cent of those contacted will agree to participate in the study. In the Canadian Study of Health and Aging, a similar percentage of those identified through provincial health registries were potentially eligible and willing to take part in the study. (7) We therefore estimate that we will need to approach approximately 152,000 potential participants in order to identify 50,000 people to take part in the CLSA (20,000 for the telephone interview cohort and 30,000 for the in-depth cohort) (see Figure 1).

The telephone interview cohort (n = 20,000) will participate in a 60- to 70-minute interview using computer-assisted telephone interview (CATI) software. CATI is an interactive computer system that aids interviewers to ask questions over the telephone. The answers are keyed directly into the computer system immediately by the interviewer thus reducing the chance of transcription errors and maximizing data security.

A home visit will be arranged with those agreeing to participate in the in-depth cohort (n = 30,000). The home interview will take the participants through the informed consent process for the physical examination and collection of biological specimens (approximately 15 minutes), and a 45-minute interview will obtain information similar to that collected from the telephone

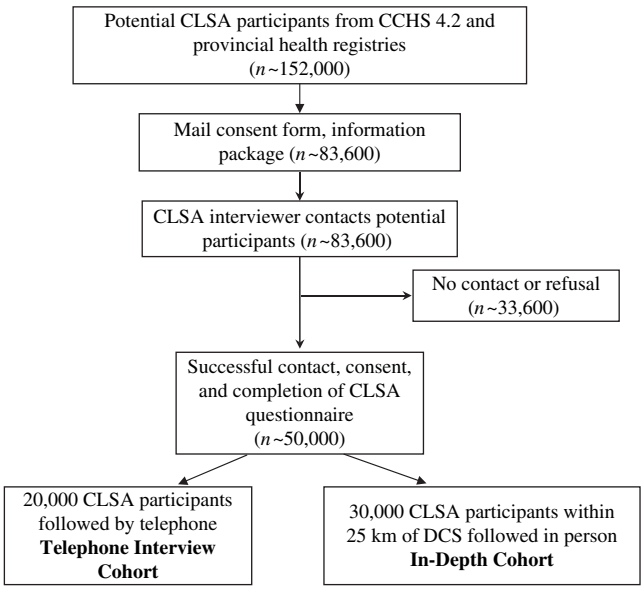

Figure 1: Data flow diagram for CLSA

interview cohort and more in-depth information on current medications. It is more feasible to obtain medication information at a participant's home rather than at the DCS because it requires viewing the participants' medications. At the end of the home interview, the participant will be scheduled for a visit to the DCS. At the site, the participant will undergo a physical examination, and will be asked to provide blood and urine samples (approximately 120 minutes).

After the baseline assessment, all 50,000 participants will be contacted every 3 years for a 60-minute CATI interview. In addition, a brief 20- to 30-minute interassessment interview will be undertaken to maintain contact and reduce losses to follow-up. The physical examination and specimen collection will be undertaken every 3 years, following the CATI interview, for participants who are involved in these aspects of the study.

In a 20-year longitudinal study, retention of participants will be critical. Several strategies will be used to minimize the number of drop-outs and losses to follow-up. To reduce barriers to participation, CLSA participants will be offered transportation to the DCS, payment of parking fees, and provision for childcare or respite care for those who require them. Data collection sites will be open on Saturdays and at least one evening during the week. If a participant is unable to travel to the DCS, alternative arrangements will be made for data collection. In addition to the major waves of data collection and the annual interassessment interviews, contact will be maintained through newsletters, birthday cards, and holiday cards.

Measurement

Measures included in the CLSA were selected by expert working groups organized around seven theme content areas: (a) biology, (b) clinical, (c) health outcomes, (d) health services, (e) lifestyle, (f) psychology, and (g) social. Measures were identified through literature reviews and chosen based on their psychometric properties (e.g., sensitivity, specificity, responsiveness), appropriateness and relevance to those between 45 and 85 years, and the feasibility, including time and cost, of administration. Table 1 lists the proposed measures for the CLSA for the in-depth and telephone interview cohorts, as well as their mode of collection, and Table 2 lists proposed biomarkers. All demographic, psychosocial, and lifestyle measures will be collected by telephone questionnaire along with activities of daily living (ADL), pain, health status, mental health, and institutional care. At baseline, information on current medication use will be collected during face-to-face home interviews for participants who will go on to the physical examination. At the physical

https://doi.org/10.1017/S0714980809990055 Published online by Cambridge University Press

Table 1: CLSA measures

Measure	CLSA Cohort (*n* = 50,000)	
	Telephone Interview Cohort (*n* = 20,000)	In-Depth Cohort Face-to-Face Interview + Clinical Examination (*n* = 30,000)
Lifestyle/Behaviour		
Alcohol use	Yes	Yes
Tobacco use	Yes	Yes
Nutrition	No	Yes
Nutritional risk	Yes	No
Physical activity	Yes	Yes
Health Status		
Activities of daily living	Yes	Yes
Instrumental activities of daily living	Yes	Yes
Pain	Yes	Yes
Sleep	No	Yes
Reproductive health	Yes	Yes
Medications	Yes	Yes
Use of technology	No	Yes
Dietary supplement use	Yes	Yes
Self-reported function	Yes	Yes
Health status/successful aging	Yes	Yes
List of chronic conditions	Yes	Yes
Chronic disease symptoms	No	Yes
Injury	Yes	Yes
Oral health	Yes	Yes
Self-reported height and weight	Yes	No
Self-reported vision and hearing	Yes	Yes
Physical Examination		
Height	No	Yes
Weight	No	Yes
Waist to hip ratio	No	Yes
Functional performance measures	No	Yes
Blood pressure	No	Yes
Vision and hearing	No	Yes
Bone density	No	Yes
Lung function	No	Yes
Heart rate variability	No	Yes
Intermedial thickness	No	Yes
Aortic calcification	No	Yes
Biological Specimens		
Blood[1]	No	Yes
Urine	No	Yes
Psychological Measures		
Mental health (depression, satisfaction with life)	Yes	Yes
Mini-cognitive function	Yes	No
Neuropsychological battery	No	Yes
Coping	Yes	Yes
Psychological distress	Yes	Yes
Social and Demographic Measures		
Social networks and social support availability	Yes	Yes
Social participation	Yes	Yes
Informal/formal care	Yes	Yes
Transitions in work and retirement	Yes	Yes
Social inequality	Yes	Yes
Wealth/income	Yes	Yes
Built environments	Yes	Yes
Migration, mobility, transportation	Yes	Yes
Education	Yes	Yes
Ethnicity, language, religion	Yes	Yes
Family and living arrangements	Yes	Yes
Paid and unpaid work	Yes	Yes
Effort–reward	Yes	Yes
Workability	Yes	Yes
Health Care Use		
Health and social service provider visits	Yes	Yes
Preventive health services	Yes	Yes
Data linkage with provincial health databases	Yes	Yes

[1] **See Table 2 for sample type**

examination, the majority of the biomedical measures will be collected, including anthropometric data, as well as assessments for physical and cognitive function, oral health, vision, and hearing. Some biomedical measures will also be collected through self-report during the telephone interview (vision, hearing, height, weight, and chronic conditions). Several tests and instruments will be administered to ascertain whether the participants have any of a number of chronic conditions including these 13: (a) cerebrovascular disease, (b) hypertension, (c) myocardial infarction, (d) angina pectoris, (e) diabetes mellitus, (f) hypothyroidism, (g) arthritis (rheumatoid and osteoarthritis of the knee, hip, and hand), (h) osteoporosis, (i) dementia, (j) depression, (k) Parkinson's disease, (l) chronic obstructive pulmonary disease (COPD), and (m) asthma. These chronic conditions were identified by the CLSA team as being

- relevant to the adult population and to the process of aging,
- able to be reliably studied in a sample of 30,000 individuals,
- conditions that are understudied with respect to evidence from existing population-based studies, and
- feasible to be ascertained without a physician examination.

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Table 2: Potential biomarkers to be measured in CLSA

Test Name	Sample Type
Aggrecan condroitin sulfate 846 epitope	S
Albumin	Ph
Angiotensin-converting-enzyme, genotype	Pe
Atrial natriuretic peptide (ANP)	Pe
Apolipoprotein E (apoE), genotype	Pe
B-type natriuretic peptide (BNP)	Pe
Calcium, total	Ph
Carotenoids	Ph
Complete blood count (CBC)1	Pe
Chlamydia pneumoniae serology	S
Cholesterol 2	S
Collagen type II cleavage (C2C)	S/U
Collagen type I and II cleavage (C1-2C)	S/U
C-reactive protein (CRP)	S
Creatinine	Ph/U
Cytochrome P450, genotype	Pe
Cytomegalovirus (CMV) antibodies	S
D-dimer	Pc
Dehydroepiandrosterone sulfate (DHEA-S)	S
Eicosapentanoic acid (EPA)	S
Estradiol	S
Ferritin	S
Fibrinogen	Pc
Fibrinopeptide A 3	O
Folate (RBC) 4	We
Follicle-stimulating hormone (FSH)	S
Glucose	Ph
Helicobacter pylori serology	Ph
Hemoglobin A1c (HbA1c) 5	We
High-density lipoprotein (HDL) 2	S
Homocysteine	Pe
Herpes simplex virus 1 (HSV-1) serology	S
Insulin-like growth factor 1 (IGF-1)	Ph
Insulin	Ph
Interleukin-6 (IL-6)	S
Iron-binding capacity (TIBC)	S
Leptin	Ph
Low-density lipoprotein (LDL) 2	S
Lutenizing hormone (LH)	Ph
Lipoprotein (a)	Pe
Microalbumin/creatinine ratio	U
Plasminogen activator inhibitor (PAI-1)	Pc
Platelet activity	Pc
Platelet aggregation	Pc
Procollagen type II C-propeptide (CPII)	S
Progesterone	Ph
Prolactin	Ph
Protein	U
Protein, total	Ph
Prothrombin fragment 1 + 2	Pc
Selenium 6	Pn
Serum amyloid A	S
Soluble CD40 ligand	S
Triiodothyronine, total (TT3)	S
Thyroxine, free (FT4)	S
Testosterone, free	S
Testosterone, total	S
Tissue-plasminogen activator	Pc
Triglycerides 2	S
Thyroid-stimulating hormone (TSH)	S
Vitamin A (retinol)	S
Vitamin B12 (cobalamin)	S
Vitamin C (ascorbic acid)	Ph
Vitamin D (25OH)	S
Vitamin E (alpha-tocopherol)	S
von Willebrand factor antigen	Pc
Zinc	Pn

Sample types to be stored: S = Serum; Ph = Plasma, heparin; Pe = Plasma, EDTA; Pc = Plasma, citrate; We = Whole blood, EDTA; B = Buffy coat; Bt = Buffy coat with trizol; U = Urine (no preservative); Additional sample types to be processed for genetics/epigentics: Whole blood, acid citrate, dextrose + dimethyl sulfoxide, peripheral blood mononuclear cells

As the CLSA cohort ages, the issue of older participants being unable to travel to a DCS is likely to become increasingly important. To mitigate this challenge, we will offer older participants with mobility limitations an abbreviated clinical visit at their residence. At this visit, we will conduct the clinical interview, collect anthropometric and blood pressure data, and undertake cognitive, performance, hearing, and vision assessments.

The study questionnaires will include standardized, validated instruments available in both French and English. Biological specimens (fasting and random blood sample and urine) will be collected from persons who have given consent. Specimen collection and storage will be carried out according to a standardized protocol (8).

Data Collection

All CLSA participants will be asked to provide common, questionnaire-based information obtained by CATI. At baseline, the CATI will be supplemented by a home interview for the 30,000 persons selected for physical examination and biological specimen collection. During subsequent waves, the DCS visit will be scheduled at the end of the CATI interview, and the face-to-face interview will be conducted using computer-assisted personal interview (CAPI) software during the physical examination. At the physical examination, trained health assessors will also collect anthropometric information and biological specimens according to standardized clinical protocols. A quality assurance program will be put into place to ensure the validity and reliability of the physical examination data being collected.

https://doi.org/10.1017/S0714980809990055 Published online by Cambridge University Press

An important supplement to the data collected during the CLSA will be linkage to health administration databases (e.g., publicly funded drug plans, medical services plans, hospitalization, continuing care/long-term care, and/or mortality) to collect complementary information on medication use, health services utilization, and to ascertain deaths and causes of death. Furthermore, we will carry out data linkage to specific disease registries such as cancer registries. These linkages will be done in partnership with provincial agencies after obtaining participant consent.

Biobanking and Data Storage

The biological samples will be stored and analysed for various clinical and biological markers at a centralized Biological Processing Centre (BPC) (see Figure 2). Specimens received by the BPC will be logged into a specimen reception database using barcode identification numbers. Biological specimens for future use will be stored using liquid nitrogen, a state-of-the-art method for long-term retention of biological specimens. Redundancy will be built into the sample storage strategy to reduce the possibility of sample loss. Sample aliquots from each participant will be divided and stored in two different liquid nitrogen tanks.

The need for data security and confidentiality is paramount to the integrity of the CLSA. The CLSA's goal is to protect confidentiality while maintaining the possibility of linkage for subject identification. A unique study identification number will be assigned to participants following completion of the consent process. All study forms and samples will be labelled with the unique study identifier. Each DCS will retain the information on participants seen at their site for the purposes of follow-up, but will have no information on subjects seen at other sites. All data linkage will be initiated by and overseen by the National Coordinating Centre (NCC) at McMaster University. Individual DCSs will forward all participant records to the NCC, which will work closely with the DCSs to ensure the completeness and quality of the collected data.

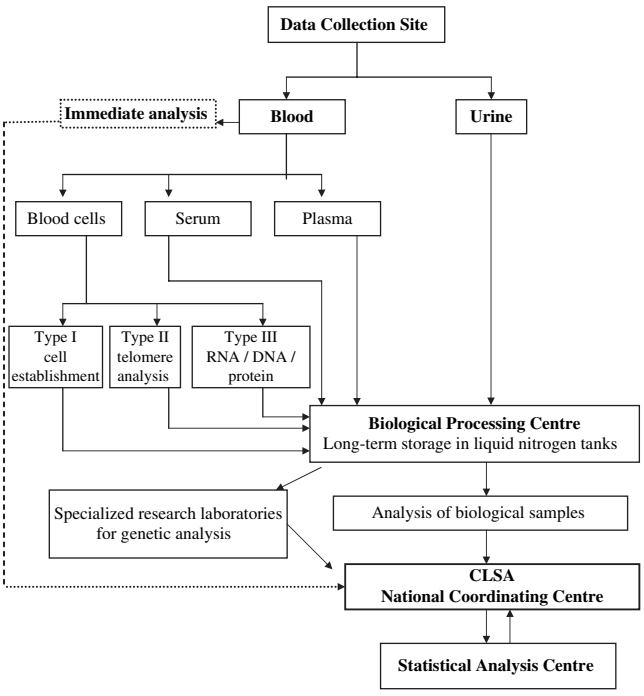

Figure 2: Biological specimen processing scheme

Questionnaire-based and physical examination data will be stored at a centralized Statistical Analysis Centre (SAC). The SAC will have access to encrypted data only and will produce a cleaned, linkable, locked dataset for each wave of data collection. The SAC will work in accordance with a memorandum of understanding (MOU) developed with Statistics Canada to ensure data integrity.

Ethical Legal and Social Issues

Potential study participants will be mailed a package containing information in lay language outlining the purpose and the nature of the study, study methods, the extent of required participation, and the anticipated risks and benefits. Study participants will be informed that their participation is voluntary, that they have the right to withdraw from the study at any time, and that any decision to participate will not affect their access to health care services. This information package will also explain that all data will be kept confidential, research will be conducted in accordance with the legal and ethical standards used for medical research, and data will never be used to identify individuals in research reports.

There are several ethical challenges to studying individuals over a long period of time in the age groups included in the CLSA. For example, the cognitive decline of some of our older participants may pose challenges for maintaining informed consent. As well, because the CLSA will be a longitudinal study going on for decades, and future (as yet undeveloped) tests and analyses cannot be specified at present, data including biological samples will be stored indefinitely. To set the stage to address these challenges, the Canadian Institutes of Health Research (CIHR) has established a committee to address the Ethical, Legal, and Social Issues (ELSI) related to CLSA. This committee is composed of lawyers, ethicists, geneticists, biologists, epidemiologists, philosophers, sociologists, and a privacy commissioner. The ELSI committee has assisted the CLSA investigators in the development of the consent process and the information package.

https://doi.org/10.1017/S0714980809990055 Published online by Cambridge University Press

Ethical challenges associated with the CLSA will be evaluated on a continuing basis by the CLSA researchers and ELSI.

Conclusions

The ultimate aim of the CLSA is to find ways to improve the health of Canadians by better understanding the processes and dimensions of aging. The CLSA will contribute to healthy aging and the maintenance of active, independent lifestyles for all Canadians. Through the voluntary participation of 50,000 persons aged 45 to 85 years, the CLSA will draw on a range of experiences from mid-life to older age. This will create a unique research resource that can be used to gain a better understanding of how the multiple aspects of health and aging, individually and in combination, have an impact on maintaining health and in the development of disease. It will provide a research platform on which nested case-control studies and intervention trials may be added.

The benefits of the CLSA will be many. The CLSA will contribute to the identification of ways to prevent disease and improve health services. We will develop a better understanding of the impact of non-medical factors such as economic and social changes on individuals as they age. The wealth of data collected will also create new knowledge of the many interrelated biological, clinical, psychosocial, and societal factors that affect healthy aging. Finally, the CLSA will facilitate the rapid adoption of sound research into health practice, programs, and policies that will produce a strengthened and more responsive health system.

Notes

1 The age range for the CLSA was changed from 40 years and older to 45 to 85. The 45-year-olds in 2008 represent the youngest of the baby boomers. At the time of the feasibility studies published in this special issue, the youngest of the baby boomers were 40 years old. The upper age for the baseline was truncated to 85 for feasibility, logistical, and cost reasons.

2 The radius for recruitment around the CLSA data collection sites was reduced from 100 km to 25 km based on the results of pilot work.

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https://doi.org/10.1017/S0714980809990055 Published online by Cambridge University Press